van Lengerich - Serial No. 09/233,443 Amendment and Summary of Interview with the Examiner

REMARKS

Summary of Interview with Examiner Webman

On August 14, 2001, the Applicant's representative, Mr. Andrew Merriam, held an interview with Examiner Edward Webman to advance prosecution in the instant application. Although the Examiner did not commit to an allowance of the instant claims, substantial progress was made in prosecuting the instantly claimed invention. The Applicant wishes to thank the Examiner for extending the courtesy of a personal interview in the instantly filed application.

Regarding the January 19, 2001 Election and Restriction Requirement, Mr. Merriam argued that all product claims should be rejoined because the intermediate and final product claims are not mutually exclusive. The Office Action of July 5, 2001 states that because water is removed by drying to make the final product, the intermediate product and final product differ by the presence of water. See page 2, first full paragraph, of the Office Action mailed on July 5, 2001. However, as Mr. Merriam pointed out, each of intermediate product claims 21-27, 29, 47-60, 66 and 67 depends from claim 1, either directly or indirectly, and claim 1 recites a drying step. Accordingly, no proper basis exists for distinguishing between an intermediate and a final product on the basis of a drying step. Therefore, the only stated basis in the July 5, 2001 Office Action for holding an intermediate and a final product mutually exclusive from each other lacks support on

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the record.

The Examiner agreed that the rule with respect to an intermediate and final product situation requires a mutually exclusive relationship between the claims. The Examiner agreed to reconsider the restriction requirement of January 19, 2001.

Regarding the September 7, 2000 Restriction Requirement separating method claims and product claims, the Examiner agreed to re-join all process claims with the instant product claims upon a finding that the product claims are allowable. Accordingly, the Applicant's representative respectfully requested the Examiner to rejoin all method claims with the instantly claimed product because the instantly claimed product contains allowable subject matter. In re Ochiai, 71 F.3rd 1565 (Fed.Cir. 1995).

Regarding the rejection of the instant claims over van Lengerich, WO 98/18610, Mr. Merriam argued that this reference is unavailable as art under 35 U.S.C. §102 or 103. The instant application was filed on January 20, 1999, less than one year after the publication of WO 98/18610 on May 7, 1998. In addition, the instant application and WO 98/18610 have the same inventor, Bernhard H. van Lengerich. Accordingly, the WO 98/18610 reference is unavailable as art against the instantly claimed invention under 35 U.S.C. §§102(a), 102(b) or 102(e). In addition, the WO 98/18610 reference is unavailable as prior art under 35 U.S.C. §103 because it is not available as prior art under 35 U.S.C. §102.

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In response, the Examiner agreed that the van Lengerich reference, WO 98/18610, is unavailable as prior art.

Regarding indefiniteness rejections, the Examiner agreed to consider arguments explaining the use of the instantly claimed terminology "substantially" as it refers to nonexpanded products. Mr. Merriam pointed out that the phrase "substantially nonexpanded" is reasonably clear and definite when read as a whole in light of the instant specification and interpreted as would an artisan of ordinary skill in the art.

Regarding instant claim 25, the Examiner agreed to allow the Applicant to spell out the acronym "ISMN," a well known acronym that refers to isosorbide-5-mononitrate. See U.S. Patent No. 4,886,820, to Gross et al., at column 1, lines 18-20, enclosed herewith. The Examiner agreed to allow the Applicant to submit a teaching reference establishing the meaning of the acronym "ISMN" as an attachment to the present amendment.

During the course of the interview, Mr. Merriam pointed out instances in which the Office Action of July 5, 2001 recited incorrect claim numbers. For instance, the cover page of the Office Action states that claims 23, 26-27, and 53 are withdrawn from consideration but these claims are included in the elected Group I claims of the January 19, 2001 restriction requirement. Also, claim 28 which is in non-elected Group II is indicated as being rejected under 35 U.S.C. §102(b) over WO 98/18610 to van Lengerich.

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Accordingly, claims 23, 26, 27, 28 and 53 should at least be included in the claims elected for prosecution.

At the end of the interview, the Examiner stated that the Applicant should anticipate a rejection of "low shear" and "low temperature". Further, the Examiner agreed to carefully review claim numbering in all outstanding issues regarding the instant claims.

The Applicant wishes to thank the Examiner for indicating that he would withdraw the restriction requirement mailed on April 5, 2000, and probably also withdraw the restriction requirement of January 19, 2001, upon a notification of the allowability of the instant claims.

Support for the Amendments to the Specification and the Cluims

The instant specification has been amended to contain a specific reference to two earlier filed provisional applications, no. 60/103,700 and no. 60/109,696, to insure the benefit of those two earlier filed applications under 35 U.S.C. §119(e)(l).

The Applicant has amended claim 25 to correct spelling, to delete redundant recitations, e.g. theophylline, and to add missing commas (,) where needed. In addition, the Applicant has spelled out the acronyms ISMN and ISDN to recite the chemical names of those compounds, respectively, isosorbide-5-mononitrate and isosorbide dinitrate. (ISDN was deleted because it was redundant with the earlier recited spelled-out version.)

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See the Summary of Interview with Examiner Webman, above. Further, the Applicant has clarified the phrase "thyroid" by amending the phrase to read "thyroid stimulating hormone". The applicant has amended claim 28 to delete the redundant recitation of "puddings." All of the revisions to claims 25 and 28 are solely editorial in nature.

The Applicant has added new claims 68-95. Support for new claims 68 and 92 can be found, for example, in the instant specification at page 13, lines 5-11. Support for new claim 69 can be found, for example, in the instant specification at page 14, lines 15-17. Support for new claims 70-72, 75-77 and 80-82 can be found, for example, on page 33, lines 10-16 of International patent application no. PCT/US97/18984 filed on April 27, 1997 in the name of Bernhard van Lengerich, and published under International Publication No. WO 98/18610 on May 7, 1998, the disclosures of which were incorporated by reference in their entireties in the instant specification at page 6, lines 11-17. Support for new claim 85 can be found, for example, in originally filed claim 1, page 10, line 17 to page 13, line 18, and on page 33, lines 10-16 of said copending International patent application no. PCT/US97/18984 and International Publication No. WO 98/18610. Support for new claims 73-74, 78-79, and 83-84 can be found, for example, on page 27, line 30 to page 28, line 1 of the instant specification. Support for new claim 86 can be found, for example, on page 17, lines 9-12 of the instant

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specification. Support for new claims 87, 90 and 91 can be found, for example, on page 13, lines 19-23 of the instant specification. Support for new claim 88 can be found, for example, on page 10, lines 17-25, page 12, lines 4-23, and page 26, lines 22-25 of the instant specification. New claims 89 and 93 are supported, for example, on page 8, line 29 to page 9, line 4, and page 12, lines 16-20, and 24-26. New claim 94 is supported, for example, at page 15, line 19 to page 16, line 5. Support for new claim 95 is found, for example, at page 1, lines 5-15, page 7, lines 9-11, page 10, lines 27-30, page 12, lines 1-3. and page 30, lines 23-24.

Upon entry of this amendment, claims 1-95 will stand pending in the instant application. The Applicant has elected the product of claims 21-27, 47-52, 54-60 and 66-67 for prosecution, with traverse. New claims 68-95 are drawn to a method of making the presently elected product. Claims 1-20, 28-46, 53 and 61-65 stand withdrawn from consideration by the Examiner as drawn to a non-elected invention.

The amendments to claims 25 and 28 are more clearly shown in the enclosed "Version with Markings to Show Changes Made".

Response to Restriction Requirement

Applicant has elected intermediate product claims 21-27, 29, 47-60 and 66-67, with traverse, in prosecuting the instantly claimed invention. However, as discussed in the interview with Examiner Webman, both the intermediate product claims and the

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method claims of the instantly claimed invention recite a drying step and so are not distinguishable from the final product claims as regards the presence of water. Please refer to the Summary of the Interview with Examiner Wobman, above. Further, the instant method claims are allowable and should be rejoined with the instant product claims, as discussed in the Summary of Interview with Examiner Webman, above. Accordingly, the Applicant respectfully requests rejoinder of all claims in the instant application. In re Ochiai, 71 F.3rd 1565 (Fed.Cir. 1995).

Rejections of the Claims

Claims 21-22, 24-25, 47-60 and 66-67 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is respectfully traversed.

The rejection states that claims 21, 23, 66 and 67 are indefinite regarding the phrase "substantially" in these claims, requesting a percent which quantifies the phrase "substantially." The statement of the rejection omits claims which depend from claims 21 and 23, including claims 22, 24 and 47-54. Accordingly, the Applicant reads the rejection regarding the phrase "substantially" as a rejection of claims 21-24, 47-54 and 66-67.

Each rejected claim recites the phrase "substantially non-expanded." However, no rule requires a quantitative definition for the phrase "substantially." The phrase "substantially" is often used in conjunction with another term to describe a characteristic of the claimed invention. The Courts have held the term "substantially" definite without

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any quantitative definition, so long as one of ordinary skill in the art understands what is claimed, in light of the specification. In re Nehrenberg, 280 F.2d 161 (CCPA 1960). Also, the term has been held definite in view of general guidelines contained in the specification. In re Mattison, 509 F.2d 563 (CCPA 1975).

The instant specification guides the ordinary skilled artisan to avoid producing expanded products in one or more of four ways:

By <u>not</u> removing plasticizing liquid; by selecting definite processing parameters including a low rate of extrudate per die area; by processing at a low temperature; and by selecting low pitch extruder screw elements to increase the degree of fill in the last extruder barrel section.

A dense, e.g. substantially non-expanded, product results which has a variable specific density of, for example, about 0.8 to about 1.5 g/cm³. See the instant specification at page 1, lines 24-27, page 2, lines 4-15, page 6, lines 19-30, page 27, line 20 to page 28, line 7, and at page 30, lines 14-22. See also the May 5, 2000 Amendment and Response to Restriction Requirement, at the paragraph bridging pages 1 and 2.

Following the guidance of the instant specification then, the ordinary skilled artisan can routinely select from exemplary processing parameters to achieve a range of specific densities. In this manner, the ordinary skilled artisan can obtain products in, for

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example, densities ranging from non-expanded to substantially non-expanded.

In an example of numerical guidance for products that are "substantially nonexpanded", the instant specification discloses a range of specific densities, in which range substantial expansion has not taken place, i.e., 0.8 g/cm³ to 1.5 g/cm³. See the instant specification, for example, at page 30, lines 20-22. In contrast, expanded products such as those produced in EP 0465364 A1, to Katzen, have densities from 0.1 to 0.3 g/cm³. See the instant specification at, for example, page 2, lines 4-10. The ordinary skilled artisan would deduce from this that the density of a product can serve as one quantitative guide for the expansion of the instantly claimed product.

Based on the examples given in the preceding two paragraphs, the instant specification provides a reasonable and clear description to the ordinary skilled artisan as to the meaning of the term "substantially" as instantly claimed. The instant specification therefore allows the ordinary skilled artisan to understand the meaning of the term "substantially" as it is instantly claimed, in light of the specification. The instant claims are thus reasonably clear and definite. The Applicant respectfully requests the reconsideration and the withdrawal of the rejection of the instant claims with regard to the phrase "substantially".

Claim 25 stands rejected as indefinite. The rejection does not include claim 56,

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which is dependent from claim 25. Accordingly, the Applicant reads the rejection as applying to claims 25 and 56. The rejection alleges that claim 25 includes redundant recitations of species, e.g. nifedipine, misspellings, missing commas, indefinite phrases referring to generic metal salts, e.g. "barium salts", and unspelled acronyms "ISMN" and "ISDN". The Applicant respectfully traverses this rejection.

Regarding metal salts, the ordinary skilled artisan would know that metal salts of encapsulants as generally recited will fall within the scope of the instant claims. The mere fact that many of such salts are known does not render the claims indefinite. For example, one of ordinary skill in the art would understand the definition of "barium salts", "manganese salts" and "magnesium salts".

Regarding alleged errors in spelling, punctuation, allegedly indefinite acronyms and redundant recitations of species, the Applicant does not accede to the correctness of the Examiner's position. The acronyms ISMN and ISDN refer to well-known isosorbide compounds. Please refer to the Summary of the Interview with Examiner Webman. above. Nevertheless, the Applicant has corrected all punctuation and spelling in the instant claim 25 and has amended claim 25 to remove redundant recitations of various bioactive and encapsulant species. Further, the Applicant has spelled out the acronyms. ISMN and ISDN, to recite their respective nitrates of isosorbides. Accordingly, claim 25

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is reasonably clear and definite.

For all of the above reasons, the Applicant respectfully requests the favorable reconsideration and the withdrawal of the indefiniteness rejection of claim 25.

Claims 21-22, 24-25, 28-29, 47-52, 54-60 and 66-67 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/18610 to van Lengerich. The van Lengerich publication is discussed in the present specification at page 6, lines 11-24. However, as discussed in the interview of August 14, 2001, this reference is not available as prior art against the invention instantly claimed. Accordingly, the applicant respectfully requests the reconsideration and the withdrawal of all rejections of the instant claims over the WO 98/18610 reference.

Please note that claims 23-24 recite a ground cookie or ground cracker matrix which is not disclosed in any art reference. Additionally, claim 27 recites specific enzymes which are not recited in any art reference. Still further, pentosans in instant claim 46 are not recited in any art reference. In addition, contrary to the Examiner's assertion, process steps in a product-by-process claim are given patentable weight where they affect the properties or characteristics of the product obtained.

For the above reasons, the Applicant respectfully requests the reconsideration and the withdrawal of the rejection of all of the instant claims over van Lengerich.

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Regarding new claims 68-84 and 86-95, each depends, directly or indirectly, from one of the allowable independent claims 1, 30, or 41. New independent claim 85 recites encapsulation with at least one plasticizable matrix material and a substantially nongelatinized starch, and use of an extrusion rate per die area of less than about 5 kg/h per mm², and a multiple aperture extrusion die, which are not taught or suggested by the references of record. Accordingly, each of claims 68-95 is currently in condition for allowance.

"Low Shear" and "Low Temperature"

The phrases "low shear" and "low temperature" are reasonably clear and definite. Although these terms are relative, the specification and the art of record each provides ample description for the ordinary skilled artisan to understand the definition of these terms. As definiteness is not considered in a vacuum, all of the instant claims comport with the requirements of 35 U.S.C. §112, second paragraph. See MPEP §2173.02.

The instant specification teaches that the multiple variables that determine the heat and shear while admixing ingredients should be selected so as not to deleteriously affect or decompose an encapsulant and so as not to lose or evaporate the encapsulant. See the instant specification at, for example, page 1, lines 15-20. The amount of shear or heat that would destroy an encapsulant depends on, among other things:

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Temperature, mechanical energy input, pressure, extruder screw pitch, configuration of admixing elements, flow rate, the presence or absence of venting, orifice diameter, and plasticizer concentration. See the instant specification at, for example, page 25, lines 21-28.

A temperature of about 5-50°C, for example, would not destroy some more sensitive encapsulants such as microorganisms. See the instant specification at, for example, page 25, lines 6-11, and at page 31, line 22 - page 32, line 6. In general, a specific mechanical energy input should total less than about 150Wh/kg. Plasticizer concentrations are discussed, for example, at page 13, line 31-page 14, line 7, of the instant specification. Extrusion rate/die area is discussed, for example, in the instant specification in those portions added by the Amendment and Response to Restriction Requirement of May 5, 2000, in the paragraph bridging pages 1-2. The Amendment of May 5, 2000 adds text in the instant specification at page 27, line 30. Low mechanical energy input extruder design is discussed, for example, at page 27, lines 5-17, of the instant specification. Accordingly, the instant specification clearly and reasonably defines several parameters that are used in arriving at desired shear and temperature in admixing.

For all the above reasons, the instantly recited phrases "low shear" and "low temperature" are reasonably clear and definite.

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Based on the foregoing, the Applicant submits that the instant claims are currently in condition for allowance. An early and favorable action on the merits is earnestly solicited.

A request for a one-month extension of time and a Supplemental Information

Disclosure Statement are being filed concurrently herewith.

A check in the amount of \$588.00 is enclosed herewith to cover the fee for the additional claims.

If any fees are due, please charge our deposit account no. 501032.

Respectfully submitted,

Andrew E.C. Merriam Registration No. 47,268

Hollander Law Firm, P.L.C. Suite 305, 10300 Eaton Place Fairfax, Virginia 22030 (703) 383-4800

November 5, 2001

Enclosure:

"Version with Markings

to Show Changes Made"
Check for \$588.00 to cover cost of
adding new claims

CERTIFICATE OF MAILING

I hereby certify that this correspondence dated 11/5/01 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on 11/5/01.

HOLLANDER LAW FIRM, P.L.C.

Suite 305

10300 Eaton Place Fairfax, Virginia 22030

Date: 1//5/01

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IN THE SPECIFICATION:

On page 1, before the first paragraph, a new paragraph is inscrted.

IN THE CLAIMS:

Claims 25 and 28 are amended as follows:

25. (Amended) An encapsulated product obtained by the method of claim 1 wherein said encapsulant is at least one member selected from the group consisting of: acepromazine, acetaminophen, acetohexamide, acetohydroxamic acid, [acetycholine] acetylcholine, acetylcysteine, acyclovir, albendazole, alclometasone dipropionate, allopurinol, alprazolam, alprostadil, amcinoide, amantadine, amdinocillin, amikacin, amiloride, aminocaproic acid, aminophylline, aminosalicylate, [aminosalicyllic] aminosalicylic acid, amitriptyline hydrochloride, ammonium chloride, amobarbital, amodiaquine hydrochloride, amoxapine, amoxicillin, amphetamine sulfate, amphotericin, ampicillin, amprolium, acetazolamide, acetyldigoxin, acetylsalicylic acid, anileridine. anthraline, antipyrine, antivenin, apomorhine, apraclonidine, ascorbic acid, [aspirin.] acromycin, atropine, amoxycillin, anipamil, azaperone, azatadine maleate, azathioprine, azithromycin, aztreonam, bacampicillin, bacitracin, baclofen, [barium salts,] beclomethasone [diproionate] dipropionate, belladonna extract, bendroflumethiazide,

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benoxinate hydrochloride, benzethonium chloride, benzocaine, benzonatate, benzthiazide, benztropine mesylate, betain, betamethasone, betaxolol, betanechol chloride, biotin, biperiden, bisacodyl, bismuth, botulism antitoxin, bromocriptine mesylate, bromodiphenhydramine hydrochloride, bumetanide, bupivacaine, busulfan, butabarbital sodium, butalbital, combinations of butalbital, caffeine, [and]aspirin and codeine, beta-carotene, calcifediol, calcium carbonate, calcium citrate, [calcium salts,] candicidin, captopril, carbachol, carbamazepine, carbenicillin indanyl sodium, carbidopa, carbinoxamine maleate, carboprost tromethamine, carboxymethylcellulose, carisoprodol, casanthranol, cascara, castor oil, cefaclor, cefadroxil, cefamandole [nafate], cefazolin, cefixime, cefoperazone, cefotaxime, cefprozil, ceftazidime, cefuroxime axetil, cephalexin, cephradine, chlorambucil, chloramphenicol, chlordiazepoxide, chloroquine phosphate, chlormadinone acetate, chlorothiazide, chlorpheniramine maleate, chloroxylenol, chlorpromazin, chlorpropamide, chlorprothixene, chlorprothixene, chlortetracycline bisulfate, chlortetracycline hydrochloride, chlorthalidone, chlorzoxazone, cholecalciferol, cholera vaccine, chromic chloride, chymotrypsin, cimetidine, cinoxazin, cinoxate, ciprofloxacin, cisplatin, clarithromycin, clavulanate potassium, clemastine fumarate, clidinium bromide, clindamycin hydrochloride, palmitate and -phosphate, clioquinol, clofazimine, clofibrate, clomiphene citrate,

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clonazepam, cinnarizine, clonidine hydrochloride, clorsulon, clotrimazole, cloxacillin sodium, cyanocobalamin, cocaine, coccidioidin, cod liver oil, codeine, colchicine, colestipol, corticotropin, cortisone [corisone] acetate, cyclacillin, cyclizine hydrochloride. cyclobenzaprine hydrochloride, cyclophosphamide, cycloserine, cyclosporine, cyproheptadine hydrochloride, cysteine hydrochloride, danazol, dapsone, dehydrocholic acid, demeclocycline, desipramine, desoximetasone, desoxycorticosterone acetate, dexamethasone, dexchlorpheniramine maleate, Dexpanthenol, dextroamphetamine, dextromethorphan, diazepam, diazoxide, dibucaine, dichlorphenamide, dicloxacillin sodium, dicyclomine, dienestrol, diethylpropion [hydrochlorid] hydrochloride. diethylstilbestrol, diflunisal, digitalis, dicoumarol, digitoxin, digoxin, dihydrocrgotamine, dihydrostreptomycin, dihydrotachysterol, dihydroxyaluminium aminoacetate, dihytoxyaluminium sodium carbonate, diltiazem hydrochloride, dimenhydrinate, dimercaprol, diphenhydramine hydrochloride, diphenoxylate hydrochloride, diphteria antitoxin, dipyridamole, disopyramide phosphate, disulfiram, dobutamine hydrochloride, docusate calcium, docusate sodium, dopamine hydrochloride, doxepin hydrochloride. doxycycline, doxycycline hyclate, doxylamine [cuccinate] succinate, dronabinol, droperidol, drotaverine, dydrogesterone, dyphylline, guaifenesin, enalapril maleate, analaprilat, ephedrine, epinephrine, equilin, ergocalciferol, ergoloid mesylates,

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ergonovine maleate, ergotamine tartrate, erythrityl tetranitrate, erythromycin, estradiol, estriol, estrogene, estrone, estropipate, ethcrynic acid, ethambutol hydrochlorid, ethchlorvynol, ethinyl estradiol, ethionamide, ethopropazine hydrochloride, ethotoin, ethynodiol diacetate, etidronate disodium, etoposide, eugenol, famotidine, fenoprofen, ferrous fumatate, ferrous gluconate, ferrous sulfate, flucytosine, fludrocortisone acetate, flunisolide, fluocinolone acetonide, fluocinonide, fluorescein sodium, fluorometolone, fluorouracil, fluoxymesterone, fluphenazine, flurandrenolide, flurazpam, flurbiprofen, folic acid, furazolidone, flunitrazepam, furosemide, gemfibrozil, gentamicin, gentian violet, glutarate, glutathimide, glycopyrrolate, chorionic gonadotropin, gramicidin, griseofulvin, guaifenesin, guanabenz, guanadrelsulfate, halazone, haloperidol, haloprogin, halothane, heparin calcium, hepatitis virus vaccine, hetacillin potassium, hexylresorcinol, histamine phosphate, histidine, homatropine, histoplasmin, hydralazine hydrochloride. hydrochlorothiazide, hydrocodone bitartrate, hydrocortisone, hexobarbital, hydroflumethiazide, hydromorphone hydrochloride, hydroquinone, hydroxocobalamin, hydroxyamphetamine, hydroxychloroquine sulfate, hydroxyprogesterone caproate. hydroxyurea, hydroxine hydrochloride, hydroxine pamoate, hyoscyamine, hyoscyamine sulfate, ibuprofen, ifosfamide, imipramide, imipramide hydrochloride, indapamide, indomethacin, insulin, inulin, iocetamid, iodoquinol, iohexol, iopamidol, ipecac, ipodate

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calcium, ipodate sodium, isocarboxacid, isoetharine hydrochloride, isoflurane, isoniacid, isopropamide iodine, isoproterenol hydrochloride, isosorbide dinitrate, isotretenoin, isoxsuprine hydrochloride, kanamycin sulfate, ketoprofen, ketoconazole, labetalol hydrochloride, lanolin, leucine, leucovorin calcium, levamisole hydrochloride, levocarnithine, levodopa, levonorgestrel, levorphanol tartrate, levothyroxine sodium. lidocaine, lincomycin hydrochloride, lindane, liothyronine sodium, liotrix, lisinopril lithium carbonate, loperamide hydrochloride, loracarbef, lonetil, lorazepam, lovastatin, loxapine, lysine, mafenide acetate, [magaldrte] magaldrate, magnesium carbonate, [magnesiumchloride] magnesium chloride, magnesium gluconate, magnesium oxide, other magnesium salts, [malathinon] malathion, manganese salts, manganese, maprotiline hydrochloride, mazindol, [measle] measles virus vaccine, mebendazole, mebrofenin, mecamylamine hydrochloride, meclizine hydrochloride, meclocycline, meclofenamate sodium, medroxyprogesterone acetate, mefenamic acid, megestrol acetate, meglumine, melphalan, menadiol sodium diphosphate, menadione, menotropine, meperidine, mephenytoin, mephobarbital, meprednisone, meprobamate, mercaptopurine, mesoridazine besylate, mestranol, metaproterenol sulfate, metaraminol bitartrate, methacycline hydrochloride, methadone hydrochloride, methamphetamine hydrochloride, methazolamide, methdilazine, methenamine, methicillin sodium, methimazole,

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methionine, methocarbamol, methotrexate, methoxsalen, methoxyflurane, methsuximide, methyclothiazide, methylbenzethonium chloride, methyldopa, methylergonovine maleate, methylphenidate hydrochloride, methylprednisolone, methyltestosterone, methysergide malcate, metoclopramide, metolazone, meoprolol tartrate, metronidazole, metyrapone, metyrosine, mexiletine hydrochloride, mexiletine hydrochloride, miconazole, minocycline hydrochloride, minoxidil, mitomycin, mitotane, molindone hydrochloride, monobenzone, morphine sulfate, mupirocin, medazepam, mefruside, methandrostenolone, methylsulfadiazine, nadolol, nafcillin, nafcillin sodium, nalidixic acid, nalorphine, naloxone, nandrolone decanoate, nandrolone phenpropionate, naproxen, natamycin, neomycin, neomycin sulfate, neostimine bromide, niacin, nitrofurantoin nalidixic acid, nifedipine, nitrazepam, nitrofurantoin, nitroglycerine, nitromerson, nizatidine, nonoxynol 9, norethindrone, norethindrone acetate, norfloxacin, norgestrel, nortriptyline hydrochloride, noscapine, novobiocin sodium, nystatin, opium, oxacillin sodium, oxamniquine, oxandrolone, oxazepam, oxprenolol hydrochloride, oxtriphylline, oxybenzone, oxybutynin chloride, oxycodone hydrochloride, oxycodone, oxymetazoline hydrochloride, oxymetholone, oxymorphone hydrochloride, oxyphenbutazone, oxytetracycline, padimate, [panreatin] pancreatin, pancrelipase, papain, panthenol, papaverin hydrochloride, parachlorophenol, paramethasone acetate, paregoric,

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paromomycin sulfate, penicillamine, penicillin, penicillin derivatives, pentaerythritol tetranitrate, pentazocine, pentazocine hydrochloride, pentazocine salts, pentobarbital sodium, perphenazine, pertussis, phenacemide, phenazopyridine hydrochloride, phendimetrazine tartrate, phenelzine sulfate, phenmetrazine hydrochloride, phenobarbital, phenophtalein, phenoxybenzamine hydrochloride, phentermine hydrochloride, phenylalanine, phenylbutazone, phenylephrine hydrochloride. phenylpropanolamine hydrochloride, physostigmine, phytonadione, pilocarpine, pimozide, pindolol, piperazine, piroxicam plicamycin, poliovirus vaccine inactivated, polycarbophil, polymyxin b sulfate, polythiazide, potassium chloride, potassium citrate, potassium cluconate, potassium [iodine] iodide, potassium sodium tartrate, povidone iodine, pralidoxime chloride, pramoxine hydrochloride, pramezam, prazepam, praziquantel, prazosin hydrochloride, prazosin hydrochloride, prednisolone, prilocaine, primaquine, primidone, probenecid, probucol, procainamide hydrochlorid, procaine hydrochloride, procarbacine hydrochloride, prochlorperazine, prochlorperazine maleate. procyclidine hydrochloride, progesterone, proline, promazine, promazine hydrochloride, promazine, promethazine, promethazine hydrochloride, propafenone hydrochloride, propantheline, proparacaine hydrochloride, propoxycaine hydrochloride, propoxyphene hydrochloride, propoxyphene napsylate, propanolol hydrochloride, propyliodone,

Dec-5-01 1:09PM;

Sent By: HOLLANDER LAW FIRM, P.L.C.;

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propylthiouracil, propylthiouracil, protriptyline hydrochloride, pseudoephedrine hydrochloride, pumice, pyrantel pamoate, pyrazinamide, pyrethrum extract, pyridostigmine bromide, pyridoxine hydrochloride, pyrilamine maleate, pyrimethamine, pyroxylin, pyrvinium pamoate, phenacetin, phenytoin, prednisone, [uinidine] quinidine gluconate, quinidine sulfate, rabies vaccine, racepinephrine ranitidine, rauwolfia serpentina, resorcinol, ribavirin, riboflavin, rifampin, ritodrine, rubella virus vaccine, saccharin, saccharin sodium, salicylamide, salicylic acid, salsalata, scopolamine, secobarbital sodium, [selenius] selenious acid, selenium sulfate, sennaserine, simethicone, sodium ascorbate, sodium bicarbonate, sodium fluoride, sodium gluconate, sodium iodide, sodium lactate, sodium nitrite, sodium ditroprusside, sodium salicylate, spironolactone, stannozolol, streptomycin, sucralfate, sulfacetamide, sulfadiazine, reserpine, sulfadioxine, sulfamerazine, sulfamethazine, sulfamethizole, sulfamethoxazole, sulfamethoxydiazine, sulfapyridin, sulfasalazine, sulfaperin, sulfathiazole, sulfisoxazole, sulfinpyrazone, sulindac, suprofen, stilains, tamoxifen citrate, temacepam, terbutaline sulfate, terfenadine, terpin, testolacton, testosterone, tolazamide, tolbutamide, tetracaine, tetracycline, tetrahydrocycline, theophylline, thiabendazole, thiamine hydrochloride, [thiamin]thiamine, thiamylal, thiethylperazine thimerosal, thioguanine, thioridazine hydrochloride, thistrepton, thiotepa, thiothixene, threonine, thyroid stimulating hormone,

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ticarcillin, timolol, tioconazole, [titaniumdioxide] titanium dioxide, tolazamide, tolbutamide, tolmetin, tolnaftate, trazodone hydrochloride, tretinoin, triacetin, triamcinolone, triamterene, triazolam, trichorfon, trichlormethiazide, trientine hydrochloride, trifluoperazine hydrochloride, triflupromazine, trihexyphenidyl hydrochloride, trimeprazine tartrate, trimethadione, trimethobenzamide hydrochloride, trimethoprim, trioxsalen, tripelennamine, triprolidine, trisulfapyrimidine, tropicamide, trypsin, tryptohan, tuberculin, tyloxapol, tyropanoate sodium, tyrosine, tyrothricin. thyrothricin bethamethasone, thiotic acid, sotalol, salbutamol, norfenefrine, silymarin. dihydroergotamine, buflomedil, etofibrate, indometacin, urea, valine, valproic acid, vancomycin hydrochloride, vasopressin, verapramil, vidarabine, vinblastine, vincristine, vitamins, warfarin, yellow fever vaccine, zinc acetate, zinc carbonate, zinc chloride, zinc gluconate, beta acetyl digoxin, piroxicam, haloperidol, [ISMN] isosorbide 5-mononitrate, amitriptylin, diclofenac, [nifedipine,] verapamil, pyritinol, nitrendipin, doxycycline, bromhexine, [methylprdnisolone,] clonidine, fenofibrate, allopurinol, pirenyepine. levothyroxin, tamoxifen, metildigoxin, o-(beta-hydroxyethyl)-rutoside, propicillin, aciclovir mononitrate, paracetamol, naftidrofuryl, pentoxifylline, propafenone, acebutolol, L-thyroxin, tramadol, bromocriptine, loperamide, ketotifen, fenoterol, cadobelisate, propanolol, enalaprilhydrogen maleate, bezafebrate, [ISDN,] gallopamil, xantinol

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nicotinate, digitoxin, flunitrazepam, bencyclane, dexapanthenol, pindolol, lorazepam, diltiazem, piracetam, phenoxymethylpenicillin, furosemide, bromazepam, flunarizin, erythromycin, metoclopramide, acemetacin, [ranitidin]ranitidine, biperiden, metamizole, doxepin, dipotassium chloroazepate, tetrazepam, estramustine phosphat, terbutaline, captopril, maprotiline, prazosin, atenolol, glibenclamide, cefaclor, etilfrine, cimetidine, [theophylline,] hydromorphone, ibuprofen, primidone, clobazam, oxaceprol, medroxyprogesterone, flecainid, pyridoxal 5 [phosphat]phosphate glutaminate. hymechromone, etofylline clofibrate, vincamine, cinnarizine, diazepam, ketoprofen, flupentixol, molsimine, glibornuride, dimetinden, melperone, soquinolol, dihydrocodeine, clomethiazole, clemastine, glisoxepide, kallidinogenase, oxyfedrine, baclofen, carboxymethylcysteine, thioridazine, betahistine, L-tryptophan, murtol, bromelaine, prenylamine, salazosulfapyridine, astemizol, sulpiride, benzerazide, dibenzepine. [acetylsalicylic acid, miconazol]miconazole, nystatin, ketoconazole, sodium picosulfate, coltyramine, gemfibrocil, rifampicin, fluocortolone, mexiletin, [amoxicillin,] terfenadrin, mucopolysaccharides polysulfade, triazolam, mianserin, tiaprofenic acid, amezinium metilsulfate, mefloquine, probucol, quinidine, carbamazepine, L-aspartate, penbutolol, piretanide, aescin, [amitriptyline,] cyproterone, sodium valproinate, mebeverine. bisacodyl, 5-aminosalicylic acid, dihydralazine, [magaldrate,] phenprocoumon,

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amantadine, naproxen, carteolol, famotidine, methyldopa, auranofine, estriol, nadolol, levomepromazine, doxorubicin, medofenoxate, azathioprine, flutamide, norfloxacin, fendiline, and prajmalium bitartrate.

28. (Amended) A food composition comprising an encapsulated product obtained by the method of claim 1 which is selected from the group consisting of ready-to-eat breakfast cereals, snacks, soups, salads, cakes, cookies, crackers, [puddings,] ice creams, yogurts, puddings, custards, baby foods, medicinal foods, sports bars, and beverages.

Claims 68-95 are added.

HOLLANDER LAW FIRM, P.L.C.

INTELLECTUAL PROPERTY LAW **SUITE 305**

HARRY I. HOLLANDER +

+ ALSO ADMITTED IN D.C.

10300 EATON PLACE FAIRFAX, VIRGINIA 22030 TELEPHONE: 703-383-4800

AX: 703-383-4804 nollander.law@prodigy.net ANDREW E.C. MERRIAM

TRANSMISSION COVER SHEET

NOTICE: This transmittal and accompanying documents are privileged and confidential, intended only for use by addressee below and no one else. If you received this transmittal in error, please immediately call sender.

QATE: <u>December 5, 2001</u>

TELEFAX NO. <u>703-872-9310</u>

Unit 1761, Examiner Edward Webman, US PTO

FROM: Andrew E.C. Merriam

RE: U.S. Application of: van Lengerich

Serial No. 09/233,443 Filed: January 20, 1999

GROUP TOO, TOO Submitted herewith are copies of the following documents which were mailed by certificate of mailing dated November 5, 2001 in response to the Office Action dated July 5, 2001, in the above-identified application:

- AMENDMENT AND SUMMARY OF INTERVIEW WITH THE EXAMINER 1) with enclosed Version With Markings to Show Changes Made (42 pages) with certificate of mailing dated November 5, 2001.
- 2) Copy of Postcard Receipt and Check No. 13136 for \$588.00 for additional claims.
- REQUEST FOR EXTENSION OF TIME (one month) with certificate of mailing 3) dated November 5, 2001.
- Copy of Postcard Receipt and Check No. 13135 for \$110.00 for one-month 4) extension.
- THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (2 5) pages) with certificate of mailing dated November 5, 2001, and Form PTO-1449 (2 pages) (copies of references are not being faxed).
- Copy of Postcard Receipt and Check No. 13137 for \$180.00 for Information 6) Disclosure Fee.

In view of the recent mail delays, it is requested that the attached Amendment be considered by the Examiner.

Nu	nber of pages including this cover sheet:51
Tin	ne Sent:
	ou do not receive all pages clearly, call (703) 383-4800
Received from < 70	133834804 > at 12/5/01 1:15:40 PM [Eastern Standard Time]